UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,734	12/15/2005	Timo Heinrich	MERCK-3099	3735

23599 7590 01/24/2008

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER	
JARRELL, NOBLE E	

ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
01/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,734	HEINRICH ET AL.	
	Examiner	Art Unit	
	Noble Jarrell	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-14* is/are rejected.

7)☒ Claim(s) *3* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/15/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Current Status of 10 / 560734

1. Claims 1-14 are currently pending in the instant application and are being examined in the current office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the sole compounds and salts thereof, does not reasonably provide enablement for all solvates and derivatives of compounds of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. Applicants only show the preparation of the parent compounds and their salts. Applicants have not shown the preparation of any solvates or any other derivatives. Derivatives of these compounds may include prodrugs, metabolites, and so on. In, addition, Vippagunta et al. (*Advanced Drug Delivery Reviews*, **2001**, *48*, 3-26) teaches that the formation of solvates is unpredictable due to the unique nature of each compound in a series of related molecules (page 18, section 3.4). Applicants are not enabled for the preparation of stereoisomers because all that is shown on the specification is compounds with a carboxamide moiety attached to a benzofuran ring.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-2, 4-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. What derivatives of the compounds are referred to? Are the derivatives prodrugs, metabolites, and so on? What alcohol protecting groups are being referred to in claim 4? Greene lists many types of protective groups for a hydroxyl group (*Protective Groups in Organic Synthesis*, **1999**, chapter 2 table of contents, pages 17-23)

6. Regarding claim 4, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

7. Claims 10-13 provide for the use of compounds of claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-13 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-2 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bottcher et al. (US 5532241, published July 2, 1996, included in IDS). Bottcher et al. teach compounds of examples 1 (the original product), 4, and 9 (original compound produced as well as species 10-13 of the analogously prepared group). Compositions of these compounds are taught as well (column 7, line 66-column 8, line 23). Example 1 anticipates claim 1 because the structural core disclosed in the prior art and in the instant compounds are substituted wherein the variable R_1 or R_2 is methoxy (OA, where A is an alkyl group), variable m is 4, X is N, n is 0, and R_3 is CH_2OH (CH_2R_4 where R4 is OH). Example 4 anticipates claim 1 because the structural core disclosed in the prior art and in the instant compounds are substituted wherein R_1 or R_2 is cyano (or nitrile), m is 4, X is N, n is 0, and R_3 is $C(O)NH_2$. Claim 5 is anticipated because the compounds are taught as serotonin reuptake inhibitors (column 1, lines 35-55).

11. Claims 1-2 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bathe et al. (WO 02/102794, published 27 December 2003). Bathe et a. report a structure in the abstract with R_1 as cyano, m as 4, X as N, and R_3 as $C(O)NH_2$. Compositions involving this compound are taught on page 25, lines 10-19.

12. Claims 1-2 and 5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartoszyk et al. (WO 02/39989, published 23 May 2002). Bartoszyk et al. teach a compound where R_1 or R_2 is cyano, m is 4, X is N, and R_3 is $C(O)NH_2$ as a serotonin reuptake inhibitor. Compositions involving this compound are taught on from page 8, line 16 to page 10, line 10. Claims 5 is anticipated because the compounds are 5-HT reuptake inhibitors (see abstract).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bathe et al. in view of March (*Advanced Organic Chemistry*, **1999**, pages 357-62). Bathe teaches the dissolving of the same compound in the 102(b) rejection above in THF (a polar aprotic solvent) and 1 N hydrochloric acid. March shows that THF has a similar polarity (37.4) to acetone (42.2)(see table on page 361) (acetone and DMSO only differ by the presence of a sulfur atom instead of a carbon atom in acetone). One of ordinary skill in the art would see that it is obvious to try substitution of THF for DMSO as well as varying the concentration of a strong acid to obtain optimum results. Thus, claim 4 is rendered obvious by the teachings of Bathe et al. in combination with March as it would have been obvious at the time the invention was made to one having ordinary skill in the art to substitute similar polar aprotic solvents to obtain optimum yields , results, or reaction conditions as applicant has done with the above cited references before them.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 1 and 4-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 4-14 of copending Application No. 10/560737. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims contain overlapping subject material and example 3 (page 21) encompasses both sets of claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 1, 4, and 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, and 6 of copending Application No. 10/481270. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound claimed in copending application 10/481270 can be embraced by both sets of claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

19. Claims 1, 6, and 14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 9, and 18 of copending Application No. 10/539516. Although the conflicting claims are not identical, they are

not patentably distinct from each other because the second compound of example 5 of copending application 10/539516 (page 25) (the compound with a $[M+H]^+$ of 414) embraces both sets of claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

If applicants have any other copending applications that overlap with the instant application, they are invited to report them.

Specification

20. The information disclosure statement filed 12/15/05 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Allowable Subject Matter

21. Claim 3 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

22. The following is a statement of reasons for the indication of allowable subject matter: Bathe et al. report the closest prior art (see 102(b) rejection). This compound does not anticipate or render obvious compound of claim 3 because the nitrogen-containing portion of the indole ring is unsaturated, not saturated. When the indole ring is unsaturated completely, Bathe et al. do not teach a hydroxyl group attached to the indole ring, nor do they report an oxo substituent attached to the indole ring.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/
Patent Examiner
Art Unit 1624

/James O. Wilson/
Supervisory Patent Examiner
Art Unit 1624